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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,821	08/15/2001	Atsuo F. Fukunaga		2396

7590 05/21/2002

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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/930,821

Applicant(s)
Fukunaga et al.

Examiner
Joseph Weiss

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 4, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Aug 15, 2001 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 6) ☐ Other:

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DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the filter located in the proximal fitting of claims 15 & 16 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The amendment filed 4 Mar 02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: A proximal fitting with a filter located in one of its lumens as set forth in claims 15 & 16.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 15 & 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The use of a filter element within a lumen of a proximal fitting.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 13-17, 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the last line of claim 13, what is "it"?

7. Claim 19 recites the limitation "the type" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 13-14 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Dryden (US 5284160).

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In regards to claim 13, Dryden discloses a multi lumen proximal fitting, Fig 1, # 3³, which is operatively connectable to a proximal terminal (41) and comprises a rigid housing (33A) having two independent lumens (inner lumen within 33b & outer lumen between 33b & 33a) having a proximal machine end (35A/B) and a distal patient/unilimb hose end (rim/flange that interfaces with the hose ~28A) wherein said fitting may be operatively connectable to a multi-lumen proximal terminal (See fig 3 interface with 41)(See col. 5 lines 32-40), this terminal having first and second ports at its distal end forming a third and forth lumen so that when the first and second lumens of the of the fitting operatively attach to the first and second ports establish a flow path with the corresponding third and forth lumens of the proximal terminal such that the flow paths defined by the lumens are independent wherein the fitting is operatively detachable from the proximal terminal by a user at the site of use.

In regards to claim 14, discloses the lumens as being co-axial.

In regards to claim 17, Dryden discloses the lumens terminating in third and fourth distal ports and fifth and sixth proximal ports wherein the ports are co-axial.

In regards to claim 18, Dryden discloses a unilimb respiratory conduit (27/29) for artificial respiration, for use with a proximal terminal, such a terminal having lumens for ingress and egress of respiratory gasses in independent flow paths which are operatively independently connectable, (See col. 5 lines 32-40) the conduit comprising first and second lumens forming independent flow paths having a distal patient end and a proximal machine end, the distal end being operatively connectable/detachable to a patient by a user at the site of use (note interface 28A & 13B) and

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said proximal end is of said conduit is operatively connectable/detachable from a proximal terminal by a user at the site of use (note the above rejection of claim 13), wherein when they are connected at the proximal terminal the first lumen is in fluid communication with inspiratory flow path (note arrows depicting flow of gas toward the patient end) and second lumen in fluid communication with the expiratory flow (note the arrows depicting flow to the machine) wherein the first lumen is operatively connectable to the inspiratory gas via the proximal terminal, while the second lumen is operatively connectable to the expiratory outlet via a proximal terminal wherein the respiratory conduit is operatively detachable from a proximal terminal after use for independent disposal or sterilization. (See col. 5 lines 32-40)

In regards to claim 19, Dryden discloses a respiratory conduit interface device (33) for operative coupling to a unilimb, multi lumen, flexible respiratory conduit of the type described in claim 18, as noted in the above rejection to claim 18 which is herein incorporated by reference, to a respiratory device comprising a rigid housing (33A) with first and second lumens defining first and second independent flow paths and having a proximal (machine) end and a distal (patient) end and wherein said flow paths diverge from each other proximally of said distal end of said housing so that the proximal end of said first lumen is independently connectable to an inlet for a source of inspiratory gas (35B via 41B) while the proximal end of the second lumen is independently operatively connectable to an expiratory outlet, wherein the hose of claim 18 is operatively attachable to the housing for use and detachable for disposal/sterilization. (See col. 5 lines 32-40)

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Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Dryden.

In regards to claim 20, the reference noted above substantially disclose the claimed invention to include the respiratory conduit being operatively attachable and detachable (See col. 5 lines 32-40) but does not disclose the interface being “permanently” connected to a machine.

It is noted that applicant’s specification does not set forth this “permanent” attachment, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary. (See Fukunaga 4265235)

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12. Claims 15& 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dryden in view of Lorenzen (US 5715815).

In regards to both claims 15 & 16 Dryden substantially discloses the instant application's claimed invention to include the use of a filter (12), but does not explicitly disclose the use of a filter in a lumen of the connector. However, Lorenzen disclose such (element 50). The references are analogous since they are from the same field of endeavor, the respiratory arts and the same problem solving area, the interconnection of multi-lumen apparatuses to a respiratory device. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Lorenzen and used them with the device of Gross. The suggestion/motivation for doing so would have been to reduce the likelihood of pulmonary infection in a patient/user. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claim 18 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5778872. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set forth a unilimb respiratory conduit for artificial respiration, for use with a proximal terminal, such a terminal having lumens for ingress and egress of respiratory gasses in independent flow paths which are operatively independently connectable the conduit comprising first and second lumens forming independent flow paths having a distal patient end and a proximal machine end, the distal end being operatively connectable/detachable to a patient by a user at the site of use and said proximal end is of said conduit is operatively connectable/detachable from a proximal terminal by a user at the site of use, wherein when they are connected at the proximal terminal the

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first lumen is in fluid communication with inspiratory flow path and second lumen in fluid communication with the expiratory flow wherein the first lumen is operatively connectable to the inspiratory gas via the proximal terminal, while the second lumen is operatively connectable to the expiratory outlet via a proximal terminal wherein the respiratory conduit is operatively detachable from a proximal terminal after use for independent disposal or sterilization.

15. Claims 13-17 & 19-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5778872 and claims 1-20 of US Patent No. 6003511. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set forth an interface device for operably coupling a unilimb conduit to a ventilator having a housing defining two flow paths independent of each other, the housing defining two ends for each flow path (machine and conduit interface ends) the flow paths converging and diverging at the two ends of the housing, thus rendering the flow paths as being independent of each other and wherein the unilimb conduit is detachable for disposal or reuse and where the interface may be permanently attached to the ventilator.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5823184, 4637384, 4463755, 4232667, 4007737

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

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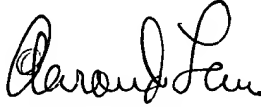
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, John G. Weiss, can be reached at telephone number (703) 308-2702. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



J. Weiss

May 16, 2002



Aaron J. Lewis
Primary Examiner